Wisconsin Department of Regulation & Licensing

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Website: http://drl.wi.gov

FOR OFFICE USE
License #:_____
Date Granted:_____
To DOE: _____

PRESCRIPTION *DEVICE*
DISTRIBUTOR SELF-INSPECTION REPORT

Application ID Number (if applicable) _____

APPLICANT NAME:_____

DBA NAME: _____

ADDRESS: _____

_____

TELEPHONE: ( ) _____

HOURS: Mon-Fri: _____ Sat _____ Sun _____

____ Change in Ownership
____ New Location
____ New Owner

PERSONNEL

Name of Owner(s): _____
_____
_____

INSPECTION

PLACE INITIALS CERTIFYING COMPLIANCE.

If the facility is in non-compliance with any portions of the "Prescription Device or Drug Distributor Self-Inspection Report" please indicate in writing why the facility is in non-compliance and when the facility will be in compliance. Return the entire "Prescription Device or Drug Distributor Self-Inspection Report" to the Board office when completed. Please make a copy for your files.

Phar 13.05

Note-for a prescription device distributor the establishment does not need to be registered with the Food and Drug Administration, if it is not a manufacturer or initial importer and distributes a prescription device from the original place of manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer and/or user. For licensure in Wisconsin, the establishment still must certify it complies with all applicable requirements of Wisconsin Administrative Code chapter Phar 13.

_____ The establishment is registered with the food and drug administration and complies with all applicable requirements of 21 USC 351, and 352 and 21 CFR 211.142(b).

Note-attach copy of the most current food and drug administration inspection.

_____ If applicable, the establishment is registered with the drug enforcement administration and complies with all appropriate requirements for registration.

Note-attach copy of the most current drug enforcement administration inspection.

Chapter Phar 13 Wisconsin Administrative Code (Distributor Requirements)

PLACE INITIALS CERTIFYING COMPLIANCE.

Phar 13.08 Personnel

_____ Only adequate personnel with education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs and services are employed.

Phar 13.09 Facility Requirements

_____ The facility must be suitable size and construction to facilitate cleaning, maintenance, and proper operation.
_____ The facility must have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.
_____ The facility must have a quarantine area for storage of prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.
_____ The facility must be maintained in a clean and orderly condition.
_____ The facility must be free from infestation by insects, rodents, birds, or vermin of any kind.

Committed to Equal Opportunity in Employment and Licensing

Wisconsin Department of Regulation & Licensing

Phar 13.10 Security Requirements

_____ Access from outside the premises is kept to a minimum and well controlled.
_____ The outside perimeter of the premises is well lighted, which includes at a minimum that access points and doorways are illuminated.
_____ Entry into areas where prescription drugs or devices are held is limited to authorized personnel.
_____ An alarm system such as a central monitoring system, or motion sensors and/or door alarms are in use to detect unauthorized entry after hours.
_____ An internal monitoring system that provides suitable protection against theft and diversion including, when appropriate, protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Phar 13.11 Storage Requirements

_____ All prescription drugs or devices stored in the facility shall be at appropriate temperatures and storage conditions as specified in the labeling of the product.
_____ If no storage requirements are established for a prescription drug or device it shall be held at controlled room temperature.
_____ Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devises, and/or logs shall be utilized to document proper storage of prescription drugs and devices when needed.
_____ The record keeping requirements in Phar 13.14 shall be followed for all stored drugs and devices at the facility.

Phar 13.13 Returned, Damaged and Outdated Prescription Drug and Device Requirements

_____ Prescription drugs and devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs and devices until they are destroyed or returned to their supplier.
_____ Any prescription drugs or devices whose immediate or sealed outer or sealed secondary container have been opened or which have been used shall be quarantined and physically separated from other drugs and devices until they are destroyed or returned to their supplier.
_____ If the conditions under which a prescription drug or device has been returned to a facility cast doubt on the product's safety, identity, strength or purity, then the product shall be destroyed or returned to the supplier.
_____ Recordkeeping requirements of Phar 13.14 shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs or devices.

Phar 13.14 Record Keeping Requirements

The distributor shall establish and maintain inventories and records of all transactions regarding receipt and distribution or other disposition of prescription drugs and devices including:

_____ The name and address of the seller or transferor and the address of the location from which the drugs or devices were shipped.
_____ The identity and quantity of the drugs or devices received and distributed or destroyed.
_____ The date of receipt and distribution or other disposition of the drugs or devices.
_____ Inventories and records must be made available for inspection and copying by the board, federal, state, and local law enforcement for a period of two years following distribution or other disposition of the drugs or devices.
_____ Records kept at the site or immediately retrievable by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of request.

Wisconsin Department of Regulation & Licensing

Phar 13.15 Written Policies and Procedures

_____ Policies and procedures shall be established, maintained and adhered to for the receipt, security, storage, inventory, and distribution of prescription drugs and devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

_____ There shall be a procedure to ensure that the oldest approved stock of a prescription drug or device is distributed first.

_____ There shall be a procedure for handling recalls and withdrawals of prescription drugs and devices.

_____ There shall be a procedure to ensure that a distributor prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

_____ There shall be a procedure to ensure that outdated prescription drugs or devices are segregated from other products and either returned to the manufacturer or destroyed. It shall include written documentation of the disposition and be maintained for two years after disposition of the outdated drugs or devices.

Phar 13.16 Responsible Persons

_____ A distributor shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug and device distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

AFFIDAVIT

I, the applicant, state that all statements herein contained are each and all strictly true in every respect. I have read the applicable Wisconsin State Statutes and Administrative Code concerning Distributor Requirements, am familiar with its provisions, and if granted a license, agree that I will abide by all of said provisions. I understand that false or forged statements made in connection with this application may be grounds for denial or revocation of the Distributor's License.

_____
Applicant Signature

_____
Date

Subscribed and sworn to before me this date:

_____, 20 _____

_____
Notary Public Signature

_____ _____
State My Commission Expires

<u>NOTE</u>: This affidavit must be signed by the applicant in the presence of the notary public on the same date.